



May 7, 2008

**ADMINISTRATIVE ORDER**  
**No. 2008 - OOIO**

**SUBJECT: Revised Rules and Regulations Governing the Registration and Licensure of Dental Laboratories in the Philippines**

**I. Rationale**

FOURmula ONE for Health is the implementation framework for reforms in the Philippines. The main objective of the regulatory reforms is to assure access to quality and affordable products, devices, facilities and services, especially those most commonly used by the poor.

The Department of Health is constitutionally mandated to protect and preserve the health of the people including oral health. In support to its mandate, Presidential Decree No. 1542, "Providing for the Registration and Licensing of Dental Prosthetic Laboratories", was issued on June 11, 1978. To implement this decree, the DOH formulated the rules and regulations. With the current advances in dentistry, the services of dental prosthetic laboratories expanded. Consistent with Executive Order No. 102 dated May 24, 1999, "Redirecting the Functions and Operations of the Department of Health", the latest revision of the rules and regulations was embodied in Administrative Order No. 28 s. 2003 and Administrative Order No. 105 s. 2003, both known as "Revised Rules and Regulations Governing the Registration, Licensure of Dental Laboratories in the Philippines". After 5 years of implementation, the Bureau of Health Facilities and Services, the main instrumentality of the DOH responsible for setting and reviewing regulatory policies and standards of health facilities, is amending A.O. No. 28 s. 2003 and A.O. No. 105 s. 2003.

**II. Objective**

These rules and regulations are promulgated in order to a) strengthen the regulatory policy that will protect the public health and at the same time ensure the safety and welfare of the community, b) ensure high compliance among stakeholders and c) consider advances in technology of dental laboratories.

**III. Scope**

The rules and regulations shall apply to any person, firm, corporation or entity, whether government or private, operating and maintaining dental laboratories.

However, the following are not covered by these rules and regulations a) dental laboratories in schools solely for teaching and training, b) those solely for manufacturing integral parts or accessories in denture making.

#### **IV. Definition of Terms**

For purposes of this rules and regulations, the following definitions are provided:

- A. BHFS – refers to the Bureau of Health Facilities and Services, the licensing and regulatory arm of the DOH.
- B. CHD – refers to the Center for Health Development, the regional office of the DOH.
- C. DOH – refers to the Department of Health.
- D. LTO – refers to the License to Operate, a formal authorization issued by the DOH to an individual, corporation, association or organization to operate a dental laboratory.
- E. PRC – refers to the Professional Regulation Commission.
- F. Dentist – a person who is a holder of valid certificate of registration and professional identification card in Dentistry, and who renders dental service within the meaning and intent of R.A. No. 9484, known as “The Philippine Dental Act of 2007”, and its Rules and Regulations.
- G. Dental Technologist – a person who is a holder of valid certificate of registration and professional identification card, and who renders technical services within the meaning and intent of R.A. No. 9484, known as “The Philippine Dental Act of 2007”, and its Rules and Regulations.
- H. Laboratory Technician – a person who renders technical services in a dental laboratory under the supervision of a dental technologist.
- I. Technical Services – the design and fabrication of oral/ dental appliances prescribed by the dentist to be installed in the patient’s mouth and surrounding tissues, repair of previously fabricated oral/ dental appliances, and consultation services to the dentist for treatment planning.
- J. Dental Laboratory – an establishment engaged in making, preparing, providing, or altering oral/ dental appliances which are prescribed by the dentist, given back to the dentist, and installed to the patient's mouth. It includes services performed in a dental prosthetic laboratory.
- K. Dental Technician – a person, either a dental technologist or a laboratory technician, who performs the various services in a dental laboratory.

- L. Appliances – artificial devices used to influence the shape of the jaws, bring the teeth and jaws into proper alignment, restore natural teeth, or replace missing teeth and craniofacial tissues.
- M. Dentures – artificial substitutes for missing teeth and adjacent tissues.
- N. Orthodontics – diagnosis and treatment of malocclusions (improper bites) by use of corrective appliances (i.e., braces, retainers, headgears).
- O. Prosthodontics – rehabilitation of oral function and esthetic by the restoration of natural teeth and/or replacement of missing teeth and craniofacial tissues with artificial substitutes (i.e., complete dentures, crowns, implant retained/ supported appliances).

## V. Guidelines

### A. General Guidelines

- 1. A license shall be issued to a dental laboratory that meets the standards and technical requirements as set forth in these rules and regulations.
- 2. An inspection tool, which prescribes the standards and technical requirements for the issuance of LTO, shall be formulated by BHFS. It shall be posted in the DOH website (<http://www.doh.gov.ph>).
- 3. A licensed dentist engaged in making, preparing, providing, or altering oral/ dental appliances solely for his/ her practice shall be exempted from securing LTO. However, a licensed dentist providing dental laboratory services to other dentists or advertising a dental laboratory through signage or publication shall be required to secure LTO.

### B. Specific Guidelines

#### 1. Classification of Dental Laboratories

##### 1.1. Ownership

- 1.1.1. Private – privately owned, established and operated with fund through donations, principal, investment or other means, by any individual, corporation, association or organization.
- 1.1.2. Government – operated and maintained partially or wholly by a national, provincial, city, municipal or other political unit; or by any department, division, board or agency thereof.

##### 1.2. Service Capability

- 1.2.1. Removable Prosthesis Services – fabrication and repair of dental prostheses that can be taken out of the mouth and put back by the patient. Any of, but not limited to, the following services is provided:
  - 1.2.1.1. Complete dentures
  - 1.2.1.2. Overdentures
  - 1.2.1.3. Orthodontic appliances

- 1.2.1.4. Temporo-mandibular joint appliances
- 1.2.1.5. Removable partial dentures
  - 1.2.1.5.1. Without metal framework
    - 1.2.1.5.1.1. Conventional acrylic dentures
    - 1.2.1.5.1.2. Thermoplastic/ flexible dentures
  - 1.2.1.5.2. With metal framework
  - 1.2.1.5.3. With metal framework (without casting)
- 1.2.1.6. Special removable appliances
  - 1.2.1.6.1. Maxillo-facial prostheses
  - 1.2.1.6.2. Implant-retained removable appliances
- 1.2.1.7. Special removable appliances (without casting)
  - 1.2.1.7.1. Maxillo-facial prostheses
  - 1.2.1.7.2. Implant-retained removable appliances
- 1.2.2. Fixed Prosthesis Services – fabrication and repair of dental prostheses that are cemented to a natural or artificial tooth. Any of, but not limited to, the following services is provided:
  - 1.2.2.1. Crown and Bridge
    - 1.2.2.1.1. Without metal alloy substructure – metal-free crowns and bridges with ceramics, composites or resins
    - 1.2.2.1.2. With metal alloy substructure – ceramics or resins fused to metal, or purely metal alloy
    - 1.2.2.1.3. With metal alloy substructure – ceramics or resins fused to metal, or purely metal alloy (without casting)
  - 1.2.2.2. Special Fixed Prosthesis
    - 1.2.2.2.1. Dental attachments
    - 1.2.2.2.2. Implant-retained fixed prostheses
  - 1.2.2.3. Special Fixed Prosthesis (without casting)
    - 1.2.2.3.1. Dental attachments
    - 1.2.2.3.2. Implant-retained fixed prostheses
- 1.2.3. Removable and Fixed Prosthesis Services – fabrication and repair of both removal and fixed dental prostheses. A combination of any of the abovementioned services is provided.
- 1.2.4. Limited Services – fabrication and repair of a specific component of dental prostheses. Only one of the following services is provided:
  - 1.2.4.1. Casting and framework soldering

## 2. Standards for a Dental Laboratory

### 2.1 Human Resources

- 2.1.1 A dentist or a dental technologist shall supervise the dental laboratory and ensure that it complies with the standards and technical requirements as set forth in these rules and regulations at all times.

2.1.2 There shall be an adequate number of dental technician, either a dental technologist or a laboratory technician, and support personnel to perform the various services in the dental laboratory.

## 2.2 Equipment/ Instruments

2.2.1 There shall be available and functional equipment/ instruments for efficient, safe and hygienic operation of the dental laboratory.

2.2.2 There shall be written and observed procedure for proper maintenance of equipment/ instruments.

## 2.3 Physical Plant

2.3.1 There shall be functional areas, based on services provided, that are clean, safe, well lighted and well ventilated.

2.3.1.1 Areas shall be reasonably free from smoke, dust and foul odor.

2.3.1.2 Areas shall be reasonably free from hazards to the life and safety of personnel and the public.

2.3.1.3 Areas shall be provided with sufficient illumination and air flow.

2.3.2 There shall be designated and separate areas for metal casting and ceramic processing.

2.3.3 There shall be smooth and orderly flow of people and supplies.

2.3.4 The dental laboratory shall be segregated and strictly for its activities.

2.3.5 It shall observe a smoke-free environment.

2.3.6 No pets shall be allowed within the premises of the dental laboratory.

2.3.7 There shall be written and observed procedure for proper maintenance of physical plant.

## 2.4 Records

2.4.1 The dental laboratory shall maintain records of work instructions that are legible, stored and readily retrievable in a suitable environment to prevent damage, deterioration and loss.

## 2.5 Personnel Safety

2.5.1 Appropriate safety devices such as casting gloves, safety goggles, laboratory gown, face mask, dust evacuator or its equivalent, shall be used.

## 2.6 Infection Control

2.6.1 There shall be written and observed procedure for infection control.

## VI. Procedural Guidelines

### A. Initial LTO

1. The applicant shall submit the following documentary requirements to the CHD:

Notarized DOH Prescribed Application Form with:

- 1.1 List of Personnel
  - 1.2 List of Equipment/ Instrument
  - 1.3 Recent 2 x 2 ID Picture of Owner, Dentist and/or Dental Technologist
  - 1.4 Photocopy of PRC Certificate of Registration and PRC Identification Card of Dentist and/or Dental Technologist
  - 1.5 Photocopy of Certificate of Training/ Record of Work Experience
  - 1.6 Photocopy of DTI/ SEC Registration (for private dental laboratory) or Issuance/ Board Resolution (for government dental laboratory)
  - 1.7 Vicinity map showing location and landmarks of the dental laboratory
  - 1.8 Laboratory lay-out with appropriate labels indicating set-up of the dental laboratory and location of the areas/ rooms
2. The applicant shall pay the non-refundable fees for registration and initial LTO, following the DOH prescribed schedule of fees, to the CHD Cashier in person or through postal money order.
  3. The CHD shall conduct inspection to determine compliance with the standards and technical requirements within 45 calendar days from receipt of complete application.
  4. The CHD shall notify the applicant of its decision not later than 45 calendar days from receipt of complete application.
  5. The applicant shall act on the deficiencies duly noted during inspection within 30 calendar days from receipt of notice of deficiency.
  6. The CHD shall issue the LTO upon full compliance to all requirements.

### B. Terms and Conditions of LTO

1. The LTO shall be issued only for the premise and person named in the application and shall not be transferable or assignable.
2. The LTO shall be posted in a conspicuous space easily seen by the public. A copy of these rules and regulations shall be readily available for reference and guidance of the dental laboratory personnel.
3. A fee shall be charged for replacement of lost or worn-out LTO.
4. Any change in the name of the dental laboratory shall require the owner to notify CHD in writing within 15 calendar days from receipt of new DTI/ SEC registration regarding change of name and to submit a photocopy of it.
5. Any change in ownership shall require the new owner to register and apply for an initial LTO.

6. In cases of transfer of location and change in service capability, the owner shall register and apply for an initial LTO.
7. A dental laboratory may continue operation while waiting for a decision on its application for LTO, either initial or renewal, unless otherwise advised or ordered to cease operation.
8. A separate LTO shall be required for dental laboratories (branches or satellites) maintained in separate premises even operating under the same owner if they perform any of the services classified under service capability.
9. Before closing down the dental laboratory, the owner shall notify the CHD in writing within 15 calendar days.

#### C. Renewal of LTO

1. Application for renewal of LTO shall be filed within 90 calendar days before the expiration date of license.
2. The applicant shall submit the following documentary requirements to the CHD:

Notarized DOH Prescribed Application Form with:

- 2.1. List of Personnel
  - 2.2. List of Equipment/ Instrument
  - 2.3. Photocopy of Current PRC Identification Card, if applicable
  - 2.4. Photocopy of Current DTI Registration, if applicable
3. If renewal of LTO is filed within 90 calendar days before the expiration date, a ten percent (10%) discount on the renewal fee shall be granted.
  4. If renewal of LTO is filed less than a year after the expiration date, surcharge equal to fifty percent (50%) of the renewal fee shall be imposed over and above the renewal fee.
  5. The LTO not renewed for more than a year after the expiration date shall be considered lapsed and registration cancelled. The dental laboratory shall register and apply for an initial LTO before it can be allowed to operate. Arrears equal to one hundred percent (100%) of the renewal fee for every year lapsed shall be imposed over and above the fees for registration and initial LTO.
  6. For any change in circumstances of the dental laboratory, the CHD shall conduct inspection to determine compliance with the standards and technical requirements within 45 calendar days from receipt of complete application.
  7. The CHD shall notify the applicant of its decision not later than 45 calendar days from receipt of complete application.
  8. The applicant shall act on the deficiencies duly noted during inspection within 30 calendar days from receipt of notice of deficiency.
  9. The CHD shall issue the LTO upon full compliance to all requirements.

#### D. Monitoring

1. All dental laboratories shall be monitored without prior notice.
2. All dental laboratory owners shall make available to the BHFS/ CHD monitoring team all pertinent records.
3. The BHFS monitoring team shall furnish the CHD a copy of the monitoring report in the soonest possible time.

#### E. Reporting

1. The BHFS shall formulate a standard reporting form.
2. The CHD shall provide the BHFS a report of dental laboratories inspected and issued an initial LTO in the soonest possible time.
3. The CHD shall furnish the BHFS the following reports on the indicated date:
  - 3.1. Annual Report of Licensed and Unlicensed Dental Laboratories (not later than January 15 of the following year)
  - 3.2. Quarterly Report on Suspension/ Revocation/ Cease-and-Desist Orders Issued (not later than the 15<sup>th</sup> day of the following month)

### **VII. Implementing Mechanism**

#### A. Responsibilities of the BHFS

1. Publishes the list of licensed dental laboratories according to their classification (ownership and service capability).
2. Assists the CHD in the inspection of dental laboratories.
3. Provides technical assistance to dental laboratories when necessary/ as requested.
4. Monitors dental laboratories at any given time within reasonable hours.
5. Coordinates with professional organizations and local government units for the enforcement of these rules and regulations.

#### B. Responsibilities of the CHD

1. Issues initial and renewal of LTO.
2. Inspects dental laboratories at a set time to determine compliance with the standards and technical requirements.
3. Provides technical assistance to dental laboratories when necessary/ as requested.
4. Monitors dental laboratories at any given time within reasonable hours.
5. Suspends or revokes LTO.
6. Issues cease-and-desist order to unlicensed dental laboratories.
7. Coordinates with professional organizations and local government units for the enforcement of these rules and regulations.
8. Investigates complaints or charges filed by any person, interested party or corporation against a dental laboratory or its personnel.



C. Responsibilities of a dental laboratory

1. Ensures compliance with the standards and technical requirements as set forth in these rules and regulations at all times.
2. Ensures that the facility is utilized solely for dental laboratory activities.
3. Maintains a standard record book reflecting ordered and finished jobs.
4. Files and maintains original prescription/ job order/ work authorization signed by the dentist.
5. Ensures that the records are available for inspection and monitoring at all times.

D. Roles of the PRC through the Board of Dentistry

1. Acts on complaints against dentists and dental technologists.

E. Roles of Professional Organizations

1. Assist in handling complaints against dentists, dental technologists and dental laboratories.
2. Report unlicensed dental laboratories to the BHFS/ CHD.
3. Assist in enforcing these rules and regulations.

F. Roles of Local Government Units

1. Report unlicensed dental laboratories to the CHD.
2. Assist in enforcing these rules and regulations.

**VIII. Validity**

The LTO issued shall be valid for the period of three (3) years and expire on the anniversary date.

**IX. Transitory Provision**

All existing dental laboratories licensed before the date of effectivity of the Rules and Regulations of R.A. No. 9484:

1. Renewal of LTO in 2008, 2009 and 2010 shall be approved even when the dental technologist does not have a valid PRC Certificate of Registration and Identification Card, provided that he/ she registers with the PRC, pursuant to Section 27 of the Rules and Regulations of R.A. No. 9484.
2. However, renewal of LTO in 2011 and beyond shall be granted only when the dental laboratory meets the standards and technical requirements as set forth in these rules and regulations.

All new dental laboratories licensed after the date of effectivity of the Rules and Regulations of R.A. No. 9484:

1. Initial LTO in 2008, 2009 and 2010 shall be approved even when the dental technologist does not have a valid PRC Certificate of Registration and Identification Card, provided that he/ she registers with the PRC, pursuant to Section 27 of the Rules and Regulations of R.A. No. 9484.
2. However, initial and renewal of LTO in 2011 and beyond shall be granted only when the dental laboratory meets the standards and technical requirements as set forth in these rules and regulations.

## **X. Violation**

Violation of P.D. 1542 and/or these rules and regulations, including the commission of the following acts by person(s) operating a dental laboratory or by person(s) under their authority:

1. Any material false statement in the application.
2. Operating, managing or maintaining a dental laboratory without valid LTO for the current year.
3. Refusal to allow inspection/ monitoring of the dental laboratory by persons authorized by the BHFS/ CHD Director during reasonable hours.
4. Any person illegally practicing dentistry for the purpose of fabricating dental appliances within the confines of the laboratory.
5. Displaying/ selling ready-made prosthetic or orthodontic appliances like retainers/ dentures of varying designs for public use/ consumption.
6. Operating unauthorized branches other than the licensed dental laboratory.
7. Putting-up misleading signboards of a dental laboratory.
8. Utilizing part of the facility for activities not related to dental laboratory operations.

## **XI. Investigation of Complaints or Charges**

The CHD Director or his duly authorized representative(s) shall investigate the complaints or charges filed by any person, interested party or corporation against a dental laboratory or its personnel. The CHD Director or his representative(s) shall verify the merit of the complaint. If upon investigation, a person(s) is found violating the provisions of P.D. 1542 and/or these rules and regulations, the CHD Director shall either suspend for a definite or indefinite period of time, cancel, or revoke the LTO of the dental laboratory without prejudice to taking the case to judicial authorities for criminal action.

## **XII. Revocation and Suspension of License**

A LTO whether issued initially or renewed, shall be suspended or revoked by the CHD Director upon violation of P.D. 1542 and/or these rules and regulations. The CHD shall notify the dental laboratory concerned, or its personnel, by registered mail the particular reasons for the suspension and revocation of its license.

### **XIII. A ppeal**

Any dental laboratory or any of its personnel aggrieved by the decision of the CHD may within thirty (30) calendar days after receipt of notice of the decision, file a notice of appeal to the DOH Office of the Secretary. Thereupon the CHD shall promptly certify and file a copy of the decision, including the transcript of the hearings on which the decision is based with the DOH Office of the Secretary for review. The decision of the DOH Office of the Secretary shall be final and executory.

### **XIV. Closure**

The CHD Director shall immediately order the closure of the facility without LTO and shall seek assistance of appropriate agency to effectively enforce the actual or constructive closure.

### **XV. Penal Provision**

Any person who violates any provision of P.D. 1542 and/or these rules and regulations shall be punished by imprisonment of not less than one month but not more than one year or by a fine of not less than two hundred pesos (P200.00) but not more than one thousand pesos (P1,000.00) or both such fine and imprisonment in the discretion of the court.


### **XVI. Repealing/ Separability Clause:**

Any administrative issuances, rules and regulations inconsistent herewith are hereby repealed, modified, or amended accordingly.

In the event that any section, paragraph, sentence, clause or word of this Order is declared invalid for any reason, the other provisions thereof shall not be affected thereby.

### **XVII. Effectivity**

These rules and regulations shall take effect fifteen (15) calendar days upon approval and publication in a newspaper of general circulation.

  
**FRANCISCO T. DUQUE, M.D., M.Sc.**  
**Secretary of Health**